UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN W. WONG

Appeal No. 2006-2043
Application 09/424,431

HEARD: October 19, 2006

Before FRANKFORT, OWENS and HORNER, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 15 and 23 through 38, all of the claims remaining in the application. Claims 1 through 14 and 16 through 22 have been canceled.

As noted on page 1 of the specification, appellant's invention relates to a method and apparatus for delivering radiation therapy, and more specifically to a method and apparatus for delivering radiation therapy during suspended ventilation of a patient. Appellant notes that during radiation for the treatment of cancer,

because of respiratory motion, a large margin is needed to ensure proper tumor coverage and that this generally leads to a large volume of healthy tissue being irradiated. Motion of the lungs and diaphragm can cause a displacement on the order of more than 2 cm for organs and a tumor being treated by radiation during a breathing cycle. Because of the large margin and irradiation of a large volume of healthy tissue, limits are placed on the dose of radiation that can be delivered to a tumor in a given treatment fraction. It has been recognized in the prior art that high dose conformal radiation in the thorax and abdomen is more effective when organ and tumor motion due to breathing can be minimized (Specification, page 3).

Appellant's specification (pages 3-4) makes note of different approaches used to address the above-noted problem in the prior art and minimize respiratory motion. One of those approaches known as "triggering" or "gating" involves an arrangement wherein the patient's respiration cycle is monitored using an external device such as a spirometer or a string-gauge to turn on the radiation beam only at a certain point in the respiration cycle. One component of this technique is to train the patient to exercise a breath-holding at the appropriate lung volume in order to extend the duty cycle of the radiation beam. Another approach is to use deep inspiration breath holding, during which time the radiation beam is activated. Appellant notes that the current approaches rely on the passive

monitoring of respiration followed by electronic or manual triggering of the radiation beam and rely on the patient to reproducibly get to the same respiratory position for each beam application. According to appellant, the inevitable variability of the prior art approaches means that a wider tolerance of the radiation margin is needed to ensure proper tumor irradiation and to address concerns for the effects of the radiation on the surrounding healthy tissue.

In the invention, appellant takes a more active approach by utilizing a method and apparatus that provides positive control over a patient's breathing by utilizing a computer controlled apparatus (10) including a ventilator assembly (13) to suspend or "freeze" patient breathing at a desired point in the respiration cycle. In the embodiment seen in Figures 1-3 of the application, once the valves (14, 16) of the ventilator assembly are closed, all air flow to the patient is stopped so that the patient cannot inhale or exhale. During this period of time when the organs and tumor are essentially immobilized, the clinician activates the radiation beam. Since the point at which the organs and tumor are immobilized can be reliably controlled, the treatment margin can be appropriately reduced, thereby enhancing the potential to escalate the radiation dose. An abort switch (36) is provided for operation by the patient to turn off the radiation machine and open one of the closed valves

(14, 16) in the event of any discomfort. Figure 5 of the application shows a second embodiment wherein a single valve (52) is used to control inhalation and exhalation.

Independent claims 15 and 33 are representative of the subject matter on appeal and a copy of those claims can be found in the Appendix to appellant's brief.

The prior art references listed in the answer as being relied upon by the examiner in rejecting the appealed claims are:

Voss	4,752,064	Jun. 21, 1988
Beran	4,815,459	Mar. 28, 1989
Rienmueller et al. (Rienmueller)	5,067,494	Nov. 26, 1991
Dietz	5,485,833	Jan. 23, 1996
Anderson et al. (Anderson)	6,436,127	Aug. 20, 2002 (filed Oct. 8, 1998)

Claims 15, 29 through 31 and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dietz in view of Rienmueller and Anderson.

Claims 23 through 26 and 34 through 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dietz in view of Rienmueller and Anderson taken further in view of Beran.

Claims 27, 28, 37 and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dietz in view of Rienmueller and Anderson as applied to claim 33 above, and further in view of Voss.[1]

Rather than attempt to reiterate the examiner's commentary with regard to the above-noted § 103 rejections and the conflicting viewpoints advanced by appellant and the examiner regarding those rejections, we make reference to the final rejection (mailed March 8, 2005) and examiner's answer (mailed November 30, 2005) for the reasoning in support of the rejections, and to appellant's brief (filed September 8, 2005) and reply brief (filed February 3, 2006) for the arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by appellant and the examiner. As a consequence of our review, we have made the determination that the above-noted § 103 rejections will not be sustained. Our reasons follow.

In rejecting claims 15, 29 through 31 and 33 under 35 U.S.C.

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[1] Since the rejection of claim 32 under 35 U.S.C. § 101 found on page 2 of the final rejection has not been repeated in the examiner's answer, we treat it as having been withdrawn. See Ex parte Emm, 118 USPQ 180 (BdApp 1957).

§ 103(a), the examiner contends (final rejection, page 3) that Dietz "teaches an apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation." The examiner then states that "[i]t should be noted that Dietz fails to teach an apparatus for suspending patient ventilation." Rienmueller is relied upon as teaching "a device with a common apparatus for suspending patient ventilation (col. 2, lines 12-19 and col. 3, lines 29-51)." The examiner then indicates that "[t]herefore, it would have been obvious to use the apparatus of Rienmueller et al. to assure that substantially no dislocation of organs or of anatomical structure ensues during a measurement or a therapy procedure (col. 2, lines 15-19)." The examiner next makes the following comments (final rejection page 3-4) concerning the failure of the proposed Dietz/Rienmueller combination to teach or suggest appellant's claimed apparatus:

> It should be further noted that Dietz/Rienmueller fails to teach a first and second operable valve adapted to control inhalation and exhalation of the patient. However it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a first and a second valve, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Furthermore, it is well know [sic] in the art or [sic] ventilators to use an inhalation and exhalation valve for controlling breathing. It would have been obvious to one having ordinary skill in the art to close any valve creating a flow to be closed to completely suspend ventilation. It should be further noted that Dietz/Rienmueller fails to teach an abort switch adapted to halt the apparatus and for administering

radiation therapy and open a closed one of the first and second selectively operable valves.

Anderson is relied upon (final rejection, page 4) as teaching "an apparatus for delivering radiation therapy with a common abort switch (col. 12, lines 3-5)." The examiner then indicates that "[t]herefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the abort switch to allow termination of radiation therapy if the correct parameters are not optimum (col. 13, lines 58-63)." It is then further urged that "Dietz/Rienmueller is fully capable of performing the same function (col. 4, lines 1-5 '494)."

Appellant contends that Anderson is directed to non-analogous art (brief, pages 8-9 and reply brief, pages 2-4). In addition, appellant argues that there is no motivation to combine Dietz, Rienmueller and Anderson, and that even if combined, the particular apparatus of the claims on appeal would not be the result, since Anderson, as well as Dietz and Rienmueller, fails to teach or suggest an abort switch that is adapted to both halt the apparatus for administering radiation and open a closed one of the first and second selectively operable valves (brief, pages 9-11 and reply brief, pages 4-8).

Like appellant, even assuming for argument sake that Anderson is directed to analogous prior art, we find nothing in the combined

teachings of Dietz, Rienmueller and Anderson that would have led one of ordinary skill in the art at the time of appellant's invention to combine the applied patents so as to result in appellant's claimed apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation. In the first place, it is unclear how or why one of ordinary skill in the art would have been led by the applied references to modify the relatively simple breathing monitor of Dietz in the manner urged by the examiner. Moreover, even assuming that the breathing monitor of Dietz were to be somehow modified or replaced by a system like that in Rienmueller, modified to include first and second selectively operable one-way valves, and then further modified to include a "kill-switch" to stop the flow of radiation as in Anderson, the resulting apparatus would still not be that required by the claims on appeal.

As noted by appellant, claim 15 on appeal requires an abort switch that is "adapted to halt the apparatus for administering radiation therapy and open a closed one of the first and second selectively operable valves." A similar abort switch is set forth in independent claim 33 on appeal for operating the single valve (52) of that embodiment. No such structure is taught or suggested in the patents relied upon by the examiner. The examiner's further assertion in the answer (page 4) that an "adapted to" clause like

that set forth in appellant's claims is "not a positive limitation" and "does not constitute a limitation in any patentable sense" is unsupported by any citation of case law and is totally without foundation. The examiner's further assertion in the answer that "it is well known in the art of medical equipment to include a kill-switch or an 'on/off' function in case there is a malfunction or parameters are not met" (page 4), is, as urged by appellant in their reply brief, an untimely and improper use of Official Notice. The examiner's contention that "Dietz/Rienmueller is fully capable of performing the same function (col. 4, lines 1-5 '494)" is also in error, since neither of those patents includes an abort switch of any kind.

As for the references to Gamble (5,111,809), Piper et al. (5,479,920) and Banner et al. (6,571,796) mentioned on page 4 of the final rejection in regard to claims 29 through 31 on appeal, but not set forth in the statement of the rejection, we share appellant's view as expressed in their brief and reply brief. We also note that appellant has repeatedly pointed out to the examiner that Banner et al. "does not qualify as prior art" (brief, page 12 and reply brief, page 9), which argument has elicited no response from the examiner. We further observe that, as pointed out by the court in In re Hoch,428.F.2d 1341,1342, 166 USPQ 406(CCPA 1970), where a reference is relied upon to support a rejection, whether or not in a minor

capacity, there would appear to be no excuse for not positively including the reference in the statement of the rejection.

In the final analysis, it is our opinion that the examiner's attempted combination of the breathing monitor of Dietz, the device of Rienmueller and the phototherapy skin treatment system of Anderson represents an improper exercise in hindsight reconstruction of the claimed subject matter based on appellant's own teachings. For that reason, and those otherwise expressed above, we will not sustain the examiner's rejection of claims 15, 29 through 31 and 33 under 35 U.S.C. § 103(a).

We have also reviewed the patents to Beran and Voss applied by the examiner in the rejections of dependent claims 23 through 28 and 34 through 38 under 35 U.S.C. § 103(a), but find nothing in either of those references that would provide for or otherwise overcome the deficiencies in the basic combination of Dietz, Rienmueller and Anderson noted above. Accordingly, the examiner's rejection of claims 23 through 26 and 34 through 36 under 35 U.S.C. § 103(a) as being unpatentable over Dietz in view of Rienmueller, Anderson and Beran, and that of claims 27, 28, 37 and 38 under 35 U.S.C. § 103(a) as being unpatentable over Dietz in view of Rienmueller, Anderson and Voss will likewise not be sustained.

In light of the foregoing, the decision of the examiner to reject claims 15 and 23 through 38 of the present application under 35 U.S.C. § 103(a) is reversed.

In addition to our determinations above, we also remand this application to the examiner to consider a rejection of claims 15 and 23 through 32 under 35 U.S.C. § 112, first paragraph, based on a lack of written descriptive support for the invention as set forth in those claims. More specifically, it is apparent that the above enumerated claims, which were added by amendment, are directed to the embodiment of Figures 1 and 2 of the application, wherein the first and second selectively operable valves set forth in the claims are the first (20) and second (21) one-way valves, while the "first valve" and "second valve" of dependent claim 25, which are each operably associated with the computer (28), are the valves (14) and (16), respectively, shown in Figure 1. The above-noted understanding of the readability of claims 15 and 25 was confirmed by appellant's representative at the oral hearing held on October 19, 2006.

The problem with independent claim 15, and thus with the claims which depend therefrom, is the recitation in that claim of the abort switch being "adapted to halt the apparatus for administering radiation therapy and open a closed one of the first and second selectively operable valves" (emphasis added). Appellant's

specification (page 10) describes the abort switch (36) seen in Figure 2 as being provided so that the patient can "turn off the radiation machine and open the valve 14 in the event of discomfort." There appears to be no descriptive support in the application as originally filed for an arrangement wherein the abort switch is adapted to operate or open one of the first and second selectively operable one-way valves (20, 21), as claim 15 seems to require.

REVERSED AND REMANDED

Charles E. Frankfort
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